



# UNITED STATES PATENT AND TRADEMARK OFFICE

*2*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,067	11/10/2004	Roch Boivin	2003946-0110(ANDI/US)	8892
24280 7590 08/16/2007 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER YOUNG, SHAWQUIA	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 08/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/507,067	BOIVIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Shawquia Young	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22, 37-46, 66, 81-88, 108 and 119-126 is/are pending in the application.
- 4a) Of the above claim(s) 84-88, 108 and 119-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 37-46, 66 and 81-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/10/04, 5/25/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

Claims 1-22, 37-46, 66, 81-88, 108 and 119-126 are currently pending in the instant application. Applicants have cancelled claims 23-36, 47-65, 67-80, 89-107 and 109-118 in a preliminary amendment.

### I. *Priority*

The instant application is a 371 of PCT/US03/07377, filed on March 7, 2003 which claims benefit of Provisional Application 60/362,883, filed on March 8, 2002 and claims benefit of 60/380, 711, filed on May 14, 2002.

### II. *Information Disclosure Statement*

The information disclosure statements (IDS) submitted on November 10, 2004 and May 25, 2006 are in partial compliance with the provisions of 37 CFR 1.97 because of an incorrect US Patent reference. Accordingly, the information disclosure statement submitted on November 10, 2004 has been partially considered by the examiner. The information disclosure statement submitted on May 25, 2006.

### III. *Restriction/Election*

#### *A. Election: Applicant's Response*

Applicants' election without traverse of the Group, claims 1-22, 37-46, 66 and 81-83 (in part), which is drawn to a compound of formula I wherein R<sub>1</sub>-R<sub>3</sub> are as defined in claim 1 excluding heteroaryl or heterocyclic; R<sub>4</sub> is hydrogen or halogen; R<sub>5</sub>-R<sub>8</sub> are as defined in claim 1; R<sub>9</sub> is -NR<sub>12</sub>R<sub>13</sub>; R<sub>10</sub> and R<sub>11</sub> are as defined in claim 1 are as

Art Unit: 1626

defined in claim 1;  $R_{12}R_{13}$  are, independently for each occurrence, hydrogen, aliphatic, heteroaliphatic, alicyclic, aryl, heteroalicyclic, heteroaryl or a protecting group; Y and Z are as defined in claim 1 excluding heterocyclic; X and n are as defined in claim 1; in the reply filed on June 1, 2007 is acknowledged.

The Examiner accepts the Applicants' grouping except for wherein  $R_{12}R_{13}$  is heteroaryl and heteroalicyclic. The Examiner will examine the above grouping excluding  $R_{12}R_{13}$  is heteroaryl and heteroalicyclic. Subject matter not encompassed by Applicants' elected group excluding  $R_{12}R_{13}$  is heteroaryl and heteroalicyclic are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

#### IV. **Rejections**

##### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

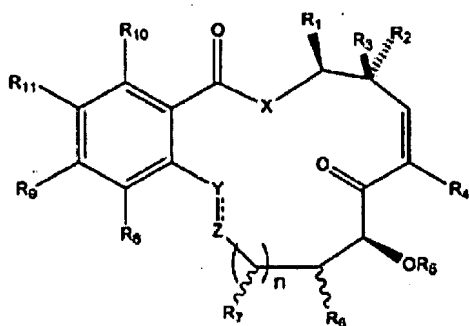
Art Unit: 1626

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22, 40, 43, 66 and 81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 10 of copending US application 10/657,910. This is a provisional obviousness-type double patenting rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Applicants' elected subject matter is a compound of formula I



, wherein R<sub>1</sub> is hydrogen, aliphatic,

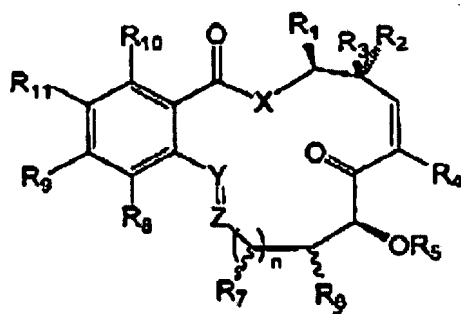
heteroaliphatic, alicyclic or aryl; R<sub>2</sub> and R<sub>3</sub> are each independently hydrogen, halogen, hydroxyl, protected hydroxyl, aliphatic, heteroaliphatic, alicyclic, or aryl; or R<sub>1</sub> and R<sub>2</sub>, when taken together, may form a substituted or unsubstituted, saturated or unsaturated cyclic ring of 3 to 8 carbon atoms or R<sub>1</sub> and R<sub>3</sub>, when taken together, may form a substituted or unsubstituted, saturated or unsaturated cyclic ring of 3 to 8 carbon atoms; R<sub>4</sub> is hydrogen or halogen; R<sub>5</sub> is hydrogen, an oxygen protecting group or prodrug moiety; R<sub>6</sub> is hydrogen, hydroxyl or protected hydroxyl; n is 0-2; R<sub>7</sub> or each occurrence, is independently hydrogen, hydroxyl or protected hydroxyl; R<sub>8</sub> is hydrogen, halogen,

Art Unit: 1626

hydroxyl, protected hydroxyl, alkyloxy or an aliphatic moiety optionally substituted with hydroxyl, protected hydroxyl,  $SR_{12}$  or  $NR_{12}R_{13}$ ;  $R_9$  is  $NR_{12}R_{13}$ ; wherein  $R_{12}$  and  $R_{13}$  are independently for each occurrence, hydrogen, aliphatic, heteroaliphatic, alicyclic, aryl or a protecting group;  $R_{10}$  is hydrogen, hydroxyl, protected hydroxyl, amino or protected amino;  $R_{11}$  is hydrogen, hydroxyl or protected hydroxyl; X is absent or is O, NH, N-alkyl,  $CH_2$  or S and Y and Z are defined as in claim 1.

Determining the Scope and Content of the Copending Application

Claim 1 of the copending application claims a pharmaceutical composition comprising a compound of the formula



, wherein  $R_1$  is hydrogen, aliphatic,

heteroaliphatic, alicyclic or aryl;  $R_2$  is methyl;  $R_3$  is hydrogen, halogen, hydroxyl, protected hydroxyl, aliphatic, heteroaliphatic, alicyclic, heteroalicyclic, aryl or heteroaryl moiety; or  $R_1$  and  $R_3$ , when taken together, may form a substituted or unsubstituted, saturated or unsaturated cyclic ring of 3 to 8 carbon atoms;  $R_4$  is hydrogen or halogen;  $R_5$  is hydrogen or an oxygen protecting group;  $R_6$  is hydrogen, hydroxyl or protected

Art Unit: 1626

hydroxyl; n is 0-2;  $R_7$  or each occurrence, is independently hydrogen, hydroxyl or protected hydroxyl;  $R_8$  is hydrogen, halogen, hydroxyl, protected hydroxyl, alkyloxy or an aliphatic moiety optionally substituted with hydroxyl, protected hydroxyl,  $SR_{12}$  or  $NR_{12}R_{13}$ ;  $R_9$  is hydrogen, halogen, hydroxyl, protected hydroxyl,  $OR_{12}$ ;  $SR_{12}$ ,  $NR_{12}R_{13}$ ,  $X_1(CH_2)_pX_2-R_{14}$  or is lower alkyl optionally substituted with hydroxyl, protected hydroxyl, halogen, amino, protected amino or  $-X_1(CH_2)_pX_2-R_{14}$ ; wherein  $R_{12}$  and  $R_{13}$  are independently for each occurrence, hydrogen, aliphatic, heteroaliphatic, alicyclic, heteroalicyclic, aryl, heteroaryl or a protecting group, or  $R_{12}$  and  $R_{13}$ , taken together may form a saturated or unsaturated cyclic ring containing 1 to 4 carbon atoms and 1 to 3 nitrogen or oxygen atoms and each of  $R_{12}$  and  $R_{13}$  are optionally further substituted as defined in claim 1;  $R_{10}$  is hydrogen, hydroxyl, protected hydroxyl, amino or protected amino;  $R_{11}$  is hydrogen, hydroxyl or protected hydroxyl; X is absent or is O, NH or  $CH_2$  and Y and Z are defined as in claim 1.

Ascertaining the Differences Between the Instant Application and the Copending

Application

The claims of the instant application are drawn to a broader compound genus than the claims of the copending application, which encompass the elected subject matter of the copending application. In the instant application, X is absent or is O, NH, N-alkyl,  $CH_2$  or S whereas in the copending application X is O.

*Finding Prima Facie Obviousness*

As mentioned above, the genus compound of the instant application encompasses the narrower genus compound in the copending application. Therefore, one of ordinary skill in the art would be motivated to prepare and claim the scope of the compounds in the instant application since the scope already in the copending application is encompassed by the scope of the elected subject matter in the instant claims. As a result, the claims are rejected under obviousness-type double patenting.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 37-46, 66 and 81-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "having the structure" or "has the structure" renders the products indefinite as the term the phrase "having the structure" or "has the structure" can be considered open-ended language when not clearly defined and therefore is including additional subject matter in the compounds of the formula I that is not described in the instant specification and is not particularly pointed out or distinctly claimed. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by amending the phrase "having the structure" or "has the structure" to read "of the structure" in claims 1, 9, 15, 22, 66 and 81.



***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22, 37-46, 66 and 81-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "prodrug moiety" in variable R<sub>5</sub> of Claims 1 and 81 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1-22, 37-46, 66 and 81-83.

**V. *Objections***

***Claim Objection-Non Elected Subject Matter***

Claims 1-22, 37-46, 66 and 81-83 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Art Unit: 1626

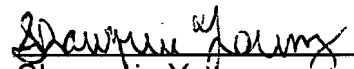
Non-initialed and/or non-dated alterations have been made to the oath or declaration for the inventor Yimin Jiang's citizenship. See 37 CFR 1.52(c).

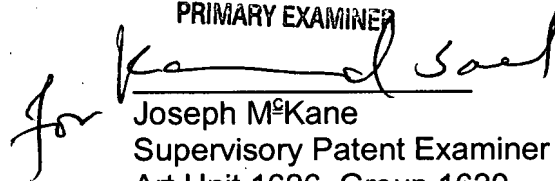
## VI. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:00 AM-2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Shawquia Young  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER  
  
for Joseph M<sup>c</sup>Kane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600